REMARKS

This Amendment is responsive to the July 11, 2006 Office Action. Claims 22-30, 32-35, 38, 41-57 are pending in this application and claims 22, 24-26, 29-30, and 38 are amended in the foregoing amendments. Claims 24, 25, and 29 are amended to place these claims in better form with the modifying word "further". Claim 30 is amended to clarify that the fluid path may comprise two or more portions and claim 26 is amended for proper antecedent basis reason . These changes are not made in response to the rejections under 35 USC § 103(a). New claims 46-57 are further added in the foregoing amendments and claims 31, 36-37, and 39-40 are cancelled in the foregoing amendments.

I. 35 U.S.C. §132(a) Objections and 35 U.S.C. §112, First Paragraph, Rejections

The specification stands objected to under 35 U.S.C. §132(a) for alleged introduction of new matter and pending claims 22-45 stand rejected under 35 U.S.C. §112, first paragraph, for lack of written description relating to the alleged new matter in the claims. The language which allegedly represents new matter in the specification is now set forth in claims 50-51 which depend from independent claims 22 and 38, respectively. This claim language states, in part, a control unit that actuates first and second pressurizing devices at substantially the same time to deliver first and second fluid media to a balloon. The new matter objection to the specification and claim rejections for lack of written description relating to the alleged new matter are traversed for the following reasons and reconsideration of the specification objection under 35 U.S.C. §132(a) and claim rejections under U.S.C. §112, first paragraph, are respectfully requested.

Applicant respectfully submits that full support is present in the original disclosure for the language questioned in the Office Action. In particular, support, as discussed in detail herein, for the language questioned in the Office Action is found in the original specification and drawings as follows:

Language Questioned	Specification Support
1. Control unit actuating the first and second pressurizing devices at substantially the same time	- Figs. 3a and 8 - Paragraphs: [0042], lines 1-3 [0046-0047]

	[0064], lines 1-3 [0065] [0074], lines 1-3 [0079], lines 4-8
2. To deliver the first and second fluid media to a balloon	- Fig. 11d - Paragraphs: [0069], lines 4-6 [0087]

From Fig. 3a, it is clear that a pair of metering pumps (68, 69) is controlled by electronic control system ("ECS" – 54). Further, it is clear from this figure and the discussion in paragraph [0042], lines 1-3 and paragraphs [0046-0047] of the specification that metering pumps (68, 69) form part of a contrast media delivery system ("CDS" – 50). Fig. 3a illustrates an embodiment of CDS (50) wherein metering pumps (68, 69) deliver fluid, namely a mixture of contrast and diluent, to a catheter inserted into the patient. A sterile connection to the catheter is provided by catheter connector (77) and sterile filter (78). Fig. 3b illustrates another embodiment of CDS (50) wherein, in place of a direct connection to the indwelling catheter, a syringe (79) is filled with a combination of contrast and diluent. However, in either embodiment, metering pumps (68, 69) are substantially simultaneously operated to provide contrast and diluent to mixing apparatus (71) which mixes the fluids to a desired concentration for delivery to a downstream patient interface device, for example, a catheter or a syringe (79) connected to a catheter. The generally simultaneous operation of metering pumps (68, 69) and, further, control by ECS (54) is described in paragraph [0046] of the specification, last sentence in particular. Accordingly, from the foregoing it is respectfully submitted that the original specification and drawings adequately discloses and describes that metering pumps (68, 69) may be operated at substantially the same time to delivery a mixture of two fluids for example, contrast and diluent, to a catheter. In fact, both pumps (68, 69) must be operated to control the concentration of contrast, if so desired, delivered to the patient, yielding the patient specific dosing ability of the electronically controlled CDS (50).

Exemplary operation of CDS (50) and control by ECS (54) is shown in Figs. 4a-4b and described in paragraphs [0056-0059]. As described in paragraph [0064], lines 1-3 and paragraph [0065], one aspect of ECS (54) is to control the CDS (50) to alter the concentration of contrast and this may only be done by the substantially simultaneous operation of metering pumps (68, 69) as described previously. Once a desired contrast level is established through

operation of pumps (68, 69), the contrast may be delivered to the patient via injection through a syringe (79) connected to a catheter or through the catheter directly as stated previously. In one particular disclosed form, the catheter may be a dual lumen catheter as disclosed in paragraph [0069], lines 4-6.

From the foregoing, it is clear that CDS (50) is controlled by ECS (54) to provide, in one aspect, a desired concentration of contrast for delivery to a patient via a catheter by substantially simultaneous operation of pumps (68, 69). Applicant further respectfully submits that the original specification provides support for this catheter to be a "balloon" catheter as claimed in independent claims 22 and 38. In Fig. 8, another embodiment of CDS (50) is shown and is designated with reference numeral "172". The embodiment shown in Fig. 8 is indicated as being another embodiment of CDS (50), as stated in paragraph [0074], lines 1-3, and may be controlled by ECS (54). Accordingly, it is clear from the original disclosure that CDS (172) may take the form of CDS (50) shown in Fig. 3a or the alternative form shown in Fig 3b, as CDS (172) in Fig. 8 is a schematic representation of the earlier versions of CDS (50) shown in Figs. 3a-3b. In paragraph [0079] at lines 4-8, it is specified that ECS (54) may control CDS (172) to deliver "[v]arying degrees of contrast media concentration". Such a result, namely different concentration levels of contrast media, may only occur when pumps (68, 69) operate substantially simultaneously.

Accordingly, based on the foregoing, Applicant respectfully submits that metering pumps (68, 69) form part of CDS (172) and may be operated substantially simultaneously to provide contrast at varying degrees of concentration fully supporting the claim language of independent claims 22 and 38. Moreover, there is no question that ECS (54) is disclosed in the original specification (and shown in Fig. 8) as controlling CDS (172) and, therefore, ECS (54) controls pumps (68, 69) in CDS (172) in like manner to what is described in the specification in connection with Figs. 3a-3b. Figs. 11a-11d schematically illustrate possible applications of the fluid delivery system including ECS (54) and CDS (172). In paragraph [0087], one possible application of the system relates to inflating a balloon on a catheter for angioplasty and other procedures. Such balloons are typically filled with a combination of contrast and diluent media (such as saline) as was identified in the Office Action with the citation of United States Patent No. 4,901,731 to Millar which, at column 6, lines 62-64, discloses inflating dilation balloon (52) with a mixture of contrast and saline. Since, the original specification describes that CDS (172)

may be used as a balloon inflation device and this device is a variation of CDS (50), pumps (68, 69) form part of CDS (172) and are operable, substantially simultaneously, to deliver a mixture of contrast and diluent for balloon inflation. Additionally, as ECS (54) is illustrated as controlling CDS (172) and, thus, pumps (68, 69) which form part of CDS (172), ECS (54) is operable to actuate pumps (68, 69) to deliver a diluted contrast solution for balloon inflation. Since the claim language at issue is fully supported in the original specification, no new matter was believed to be introduced by the Preliminary Amendment of June 13, 2005. Reconsideration of the specification objection under 35 U.S.C. §132(a) and claim rejections under U.S.C. §112, first paragraph, is therefore respectfully requested.

II. 35 U.S.C. §103(a) Rejections

Claims 22-28 and 30-45 stand rejected under 35 USC § 103(a) for obviousness over United States Patent No. 5,592,940 to Kampfe in view of United States Patent No. 4,901,731 to Millar. Claim 29 stands rejected under 35 USC § 103(a) for obviousness over Kampfe in view of Millar and further in view of United States Patent Nos. 5,569,181 to Heilman or 5,433,704 to Ross et al. Applicant respectfully traverses the rejection of these claims for the following reasons.

Kampfe discloses a device for formulating contrast media. The device (10) includes a container (12) for contrast medium and a container (14) for solvent or diluent. Containers (12, 14) are connected to a mixing chamber by feed pipes (16, 18). Feed pipes (16, 18) are brought together to form a single pipe (19) that empties into a mixing chamber (20). A delivery pipe (22) is connected to an end pipe which may be connected to a vial, bag, or syringe to fill the same. Metering elements (26, 28) are associated with feed pipes (16, 18), respectively. Metering elements (26, 28) may be peristaltic pumps. A control unit (42) is operable to control operation of metering pumps (26, 28).

Millar at column 6, lines 60-66 generally describes that dilation balloon (52) may be filled under pressure with a mixture of contrast media and saline solution as a means for inflating balloon (52). Heilman and Ross are cited in connection with claim 29 drawn to an air detector for use in a fluid delivery system.

With respect to Kampfe, it is respectfully submitted that this reference fails to teach or suggest using device (10) for catheter balloon inflation purposes. Kampfe discloses a

device (10) intended to fill "vials, bags or syringe arrangements" (See, column 8, line 4) and makes no mention of using device (10) for fluid delivery directly to a catheter for balloon inflation purposes. At most, Kampfe discloses providing contrast media at a desired contrast concentration for eventual infusion to a patient via "vials, bags or syringe arrangements". Simply, device (10) is intended to fill "vials, bags or syringe arrangements" with a desired contrast concentration mixture for eventual infusion to the patient via the "vials, bags or syringe arrangements".

Millar, as indicated previously, includes nothing more than a general teaching of balloon inflation using a contrast-diluent mixture which is well-known in the medical field. Accordingly, the combination of Kampfe and Millar fails to result in a fluid delivery system wherein first and second pressurizing devices may be actuated to deliver a first and second fluid media to a balloon on a balloon catheter as set forth in independent claims 22 and 38. The general teaching in Millar directed to balloon inflation using a mixture of contrast and diluent does not correct the lack of teaching in Kampfe with respect to fluid delivery to a balloon catheter for balloon inflation purposes. The general teaching in Millar directed to balloon inflation using a mixture of contrast and diluent does not provide motivation to one skilled in the art to use the Kampfe device as a catheter balloon inflation device. In fact, Kampfe teaches away from such a use by specifying the filling of "vials, bags or syringe arrangements" with a desired concentration mixture for delivery via the "vials, bags or syringe arrangements" to the patient. It is only Applicant's disclosure that provides a fluid delivery system which has the ability to control contrast concentration for balloon inflation applications in one aspect.

Accordingly, it is further respectfully submitted that the Office Action constructs obviousness rejections of independent claims 22 and 38 based on significant hindsight reconstruction based on Applicant's disclosure to arrive at these obviousness rejections. While a judgment on obviousness may have a component of reconstruction based on hindsight reasoning, the present Office Action develops the obviousness rejections of independent claims 22 and 38 entirely on hindsight reconstruction based on Applicant's disclosure which is impermissible. In the end, even the considerable level of hindsight reconstruction used to construct the obviousness rejections in the Office Action fails to identify a teaching of a fluid delivery system which has the ability to control contrast concentration and adapt the same for balloon inflation applications.

It is further noted that claims 22 and 38 now include clarifying language relating to the fluid path including a valve, a tube, and a per-patient connector. It is clear from a close inspection of Kampfe that the disclosed fluid path arrangement does not provide the ability to service multiple patients (or possibly even a single patient as discussed hereinabove) as no "per-patient connector" or any similar kind of structure is provided in the Kampfe fluid path. The claimed fluid path is not taught or suggested by this patent. In the Kampfe disclosure, discharge valve (66) is the terminal point of fluid delivery pipe (22) and is used a discharge point for filling "vials, bags or syringe arrangements" to be associated with the patient. Accordingly, there is a complete absence of a per-patient connector or like structure such as a valve in the Kampfe fluid path as now set forth in claims 22 and 38. Therefore, for this additional reason, claims 22 and 38 are respectfully submitted as distinguishing over Kampfe and Millar. The teachings in Heilman or Ross directed to an air detector used in a fluid delivery system do not correct the deficiencies of Kampfe in view of Millar discussed above.

Claims 24-26 and 29-30 are amended in the foregoing amendments to place these claims in better form and/or for proper antecedent basis reasons only.

III. New Claims

New claims 46-57 are added in the foregoing amendments. Claims 46-47 and 48-49 depend from independent claims 22 and 38, respectively. Claims 46 and 48 generally indicate that the first and second fluid media may be provided at increasing pressure to the balloon catheter. Specific support for this language is found in Fig. 11d and paragraph [0087] of the specification and, thus, is fully supported in the original disclosure. Such increasing fluid pressure used for balloon inflation purposes is not taught or suggested in the cited combination of Kampfe in view of Millar. As stated in paragraph [0087] of the specification such increasing fluid pressure may be used to inflate a balloon for angioplasty as an example and, as recited in new claims 47 and 49, the increasing fluid pressure may be stepped. Clearly, neither Kampfe nor Millar anticipate or suggest such a catheter balloon inflation operational mode comprising "increasing fluid pressure" or "stepped increasing pressure".

Lastly, new independent claim 52 is presented in the foregoing amendments and is similar in form to claim 38 but states that the first and second fluid pressurizing devices may be operable to deliver one or both of the first and second fluid media to a patient followed (or

preceded) by using one or both of these devices to inflate a balloon on a balloon catheter. Claim 52 is respectfully submitting as being in condition for allowance generally for analogous reasons to those set out in Applicants' previous remarks concerning claims 22 and 38. Claims 43-57 depend directly or indirectly from claim 52 and further define the method of claim 52.

IV. Conclusion

Should the Examiner have any questions regarding any of the foregoing or wish to discuss this application in further detail to advance prosecution, the Examiner is invited to contact Applicant's undersigned representative at the telephone number provided below.

Respectfully submitted,

By _____
Gregory L. Bradley
Registration No. 34,299
Attorney for Applicant